

To the FDA:

RE: DOCKET NO. 98N-1265

I send this letter as a consumer of healthcare services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer, there should be no restrictions to the delivery of a compounded medication prescribed for me, regardless of where I may live or may travel. The MOU must be amended!

The FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU must be amended!

Signed:

Denise M. Hlava

State of Residence:

Illinois

98N-1265

C3017

June 27, 1999

To the FDA,

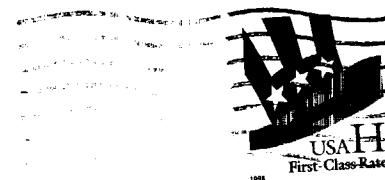
I recently received a notice for help to stop the MOW. This is not just medicine, it's compounded medicine which takes time, ups and downs and patients to fit one's individual needs.

I am a 31-one year old female who had a complete hysterectomy with removal of my ovaries at age 26. Not only losing the chance of ever having my own children, I did not expect the major changes of the emotional and physical changes and the devastating side-effects of synthetic hormones.

Until I found compounded natural hormones which are made for each individual did I find relief. Also they provide latest research and knowledge. I and other rely on them. Hormones control my mental well-being, Sexual desire, Metabolism, physical well-being. Why take this from us? The MOW must be amended or this could put patients in complete disarray! You can't play with hormones, I rely everyday on mine. It took alot of time to get well - to get my special dosage to meet my bodies needs, to feel like I did before my hysterectomy. My compounded medicine are my

98. new ovaries, Please DON'T TAKE THEM FROM ME AGAIN! I'M TOO YOUNG TO GO THROUGH ANOTHER CHANGE OF LIFE! DENISE HOLINA  
ELGIN, ILLINOIS

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